Remarks/Arguments

A favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 2-6 were presented for examination, and Claims 2-5 and 8 are now present in the case.

Claims 3-5 have been amended so that they now correctly depend on Claim 2. In the previous response, they were inadvertently amended so that they depended upon Claim 1 which was cancelled.

Claim 6 has been cancelled and replaced by "new" Claim 8.

The Examiner has rejected Claim 6 under the second paragraph of 35 U.S.C. §112 as being indefinite. Since Claim 6 depended upon Claim 2, and since the latter fails to describe a two-pulse release composition, the Examiner contends that Claim 6 does not particularly point out and distinctly claim the subject matter to which it is directed. This rejection is believed to have been overcome by the replacement of Claim 6 with "new" independent Claim 8, which claim clearly describes a two-pulse release pharmaceutical composition comprising rivastigmine as the active ingredient.

The Examiner has also rejected Claims 2-6 under 35 U.S.C. §103(a) as being unpatentable over Miyamoto et al. (USP 5,962,535) in combination with Faour et al. (USP 6,004,582). It is the Examiner's contention that since Miyamoto et al. discloses compositions containing idebenone and rivastigmine in the form of coated tablets, capsules and granules for sustained-release, and since the Faour et al. reference discloses multi-layer controlled-release compositions comprising a core with an active agent (which may be a drug like rivastigmine), a semi-permeable membrane and a water-soluble coating, and an external coat that contains an active agent for immediate-release, the instantly claimed compositions would be *prima facie* obvious to one skilled in the art from the combined teachings of Miyamoto et al. and Faour et al. Applicants respectfully disagree.

Admittedly, the broad teachings of the Miyamoto et al. reference embrace sustained-release compositions comprising idebenone and rivastigmine. However, the latter ingredient is lumped together with literally millions of compounds and, therefore, Applicants do not believe that the Miyamoto et al. reference represents a valid starting point in arriving at the compositions set forth in Claims 2-5, let alone the specific two-pulse composition set forth in "new" Claim 8.

As to the teachings of the Faour et al. reference, although it discloses multi-layer controlled-release compositions comprising a core with an active agent, a semi-permeable membrane and a water-soluble coating, and an external coat that contains an active agent for immediate-release, the active agent in the Faour et al. compositions can not only be any drug, but it can also be literally millions of non-drug compounds, e.g., insecticides, pesticides, herbicides, germicides, fungicides, etc. Quite simply, there is nothing in the Faour et al. reference which would point one skilled in the art to choose a drug from all of the non-relevant, non-drug compounds, let alone rivastigmine, and then motivate the skilled artisan to combine it with the teachings of Miyamoto et al. so as to fortuitously arrive at any of the instantly claimed compositions, let alone the specific two-pulse compositions set forth in "new" Claim 8.

In brief, the mere fact that the teachings found in the prior art could be combined as proposed by the Examiner does not make the combination obvious absent some teaching, suggestion or incentive supporting the "proposed" combination. In the present case, it is Applicants' belief that the Examiner has failed to identify any such teaching, suggestion or incentive to support the "proposed" combination of the two prior art references. Accordingly, it is clear that the combined teachings of the Miyamoto et al. and Faour et al. references do not prejudice the patentability of any of the instantly claimed compositions from a 35 U.S.C. §103 standpoint.

Withdrawal of the 35 U.S.C. §103(a) rejection of record is, therefore, respectfully requested.

In accordance with 37 CFR §1.56, the Examiner's attention is respectfully invited to the enclosed Supplemental Information Disclosure Statement and, more particularly, to the references cited in the PTO-1449 form attached thereto.

The two rejections of record having been overcome, the instant application is deemed to be in condition for allowance, and an early notice to that effect is earnestly solicited.

Since this Amendment will be deemed to have been filed more that four months from, but within five months of, the date of the Office Action, i.e., November 18, 2003, it is respectfully requested that the period for filing a response to said Office Action be extended by two months. Please charge the $420 fee required by 37 CFR §1.17(a)(2) for a two-month extension of time and the $180 fee required by 37 CFR §1.17(p) for making the additional prior art of record at this time, i.e., a total fee of $600, to Deposit Account No. 19-0134 in the name of Novartis Corporation. In this connection, an additional copy of this paper is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,

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Encls.: Supplemental Information Disclosure Statement (incl. copies of references cited therein)
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